



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,114	02/09/2001	Tsutomu Nobori	023070103031	8926

20350 7590 08/20/2004

TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/780,114

**Applicant(s)**

NOBORI ET AL.

**Examiner**

Jeanine A Goldberg

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-30,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23,25,27,29,39 and 40 is/are rejected.
- 7) ☒ Claim(s) 24,26,28 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s).**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This action is in response to the papers filed July 2, 2004. Currently, claims 23-30, 39-40 are pending.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
3. Any objections and rejections not reiterated below are hereby withdrawn in view of the amendments to the claims or applicant's remarks.
4. This action contains new grounds of rejection which are necessitated by the substantial amendments to the claims.
5. This action is FINAL.

### ***Priority***

6. This application claims priority to 09/072,914, 08/827,342, 08/459,343, 08/176,855.

With respect to Claim 23-25, 27, 29-30, 39-40, the Claim is awarded priority to the filing date of 3/26/97 for the invention of a nucleic acid sequence having SEQ ID NO: 1 which encodes the MTase. The 08/459,343 application, filed 6/2/95, which is a divisional of 08/176,855, disclosed SEQ ID NO: 1 containing a partial genomic sequence of the MTase gene and therefore did not encode MTase (since it did not contain all of the sequences indicated as coding sequences in Figure 1 and SEQ ID NO: 1 of the present application).

With respect to Claims 26, 28 the claims are awarded priority to the filing date of June 2, 1995 because the priority application 08/459,343 teaches exons 8 and 7.

## **Response to Arguments**

The response traverses the date of priority. The response asserts that the priority will be extended back to the earliest related application, namely December 1993. This argument has been reviewed but is not convincing. The newly amended claims are drawn to a fragment of MTase of SEQ ID NO: 1 comprising particular nucleotides of SEQ ID NO: 1. The claims are unclear whether the claims are drawn to fragments of SEQ ID NO: 1, where no additional sequences outside SEQ ID NO:1 are permitted to flank the particular nucleotides or whether the claim is drawn to a fragment of SEQ ID NO: 1 which comprises the particular nucleotides with any flanking sequence. As noted previously above, SEQ ID NO: 1 (all 3083 nucleotides) were first disclosed in March 26, 1997.

The response asserts that the pending claims are not directed to nucleic acids that encode a full length MTase protein. This argument has been thoroughly reviewed, but is not found persuasive because the claims are drawn to open claim language by using "comprising." As provided in MPEP 2111.03, the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Thus, it is well established that comprising allows for additional elements on the ends of the designated nucleotides. Therefore, while the claims may not be limited to full length nucleic acids encoding a full length MTase protein, the claims certainly encompass such nucleic acids. It appears, that applicants understand the differences between

Art Unit: 1634

comprising and consisting of language, as applicants have used the transitional language "consisting of" in Claims 24, 26, 28 and 30.

The response asserts that "Exon 6 is currently claimed as nucleotides 1764-1953 of SEQ ID NO: 1, and in the priority application '855 application was disclosed as nucleotides 964-1203 of SEQ ID NO: 1." The priority application of '855 appears to indicate that exon 6 is 239 nucleotides in length whereas the currently claimed exon 6 is only 189 nucleotides in length, therefore, the boundaries of Exon 6 has been changed from the priority application and the new boundaries are not afforded the benefit of the priority application '855.

Moreover, the fragment of Claim 23, namely 2754-2894 comprises a single nucleotide change between the priority document and the instant application, as previously noted. Thus, the claims are not entitled to the earlier date, as they did not comprise the instantly recited nucleic acids.

Claims 26 and 28 are each drawn to polynucleotides consisting of particular fragments which taught in June 2, 1995 as the exons.

Thus for the reasons above and those already of record, the date of priority is maintained.

**New Grounds of Rejection Necessitated by Amendment**

***Claim Rejections - 35 USC § 112-Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 23, 25, 27, 29, 39-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to "an isolated polynucleotide fragment of the MTase protein coding domain of SEQ ID NO: 1 comprising..." particular nucleotides of SEQ ID NO: 1.

The specification teaches a genomic sequence for the gene for MTase and indicates the location of exons in the polynucleotide. The specification teaches "the presumed exons are underlined; presumed introns are indicated by one or more "N" substitutions for bases in the polynucleotide sequence." Example 1 teaches a test for MTase Catalytic activity in a sample (page 23).

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved

by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, Applicant has defined only a fragment of a nucleic acid sequence. Applicant has not disclosed genomic DNA sequences, full cDNA nor disclosed regulatory sequences. The instant claims are broadly drawn to encompass nucleic acids which minimally comprise a particular exon identified by nucleotides within SEQ ID NO: 1. The claims would thus encompass not only full length genomic DNA of the MTase gene, full length cDNA, but also any splice variants comprising the particular exons claims, and any mutant sequences which minimally contain the recited exon. The partial structure of the claimed invention does not provide description for a representative scope of the claimed genus. There is no additional disclosure of physical and/or chemical properties. Weighing all factors in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of nucleotide sequence which comprising X nucleotides of SEQ ID NO: 1. Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

Art Unit: 1634

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 25, 27, 29, 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Carrera et al. (US Pat. 5,840,505, November 24, 1998).

It is noted that the inventive entity of '505 and the instant application is different.

Carrera et al. (herein referred to as Carrera) teaches a nucleic acid in Figure 1 which comprises exon 8, exon 7 and exon 6 (limitations of Claim 25, 27) (Figure 1 and SEQ ID NO: 1). As in the instant application, since Carrera teaches the boundaries of the exons, Carrera teaches a nucleic acid consisting of exons 8 and 7 (claims 26, 28). The boundaries of exon 6 differ, thus, Carrera does not specifically teach a probe consisting of exon 6. Carrera teaches using labels on the probes (col. 6, lines 30-50). The intended use of Claim 40, does not materially affect the claimed product. Thus since Carrera teaches each limitation of the instant claims, Carrera anticipates the claimed invention.



8. Claims 25, 27, 29, 39-40 are rejected under 35 U.S.C. 102(e) and 102(a) as being anticipated by Nobori et al. (US Pat. 5,571,510, November 1996).

It is noted that the inventive entity of '505 and the instant application is different.

Nobori et al. (herein referred to as Nobori) teaches a nucleic acid of SEQ ID NO: 1 which comprises exon 8, 7 and 6. Nobori teaches using labels on the probes (col. 5, lines 12-20). The intended use of Claim 40, does not materially affect the claimed product.

It is noted that Nobori does not teach any boundaries for the exons, so nucleic acids consisting of the particular exons are not taught or suggested.

Thus since Nobori teaches each limitation of the instant claims, Nobori anticipates the claimed invention.

9. Claims 25, 27, 29, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Olopade et al. (PNAS, Vol. 92, No. 14, pages 6489-6493, 1995).

It is noted that since the priority of Claims 25, 27, 29, 40 is March 26, 1997, the instant rejection is applicable.

Olopade et al. (herein referred to as Olopade) teaches a nucleic acid of human methylthioadenosine phosphorylatase (MTAP) mRNA from human chromosome 9p21. The nucleic acid comprises positions 1764-1953 of SEQ ID NO: 1 (exon 6); 2426-2548 of SE QID NO: 1 (exon 7) and 2838-2876 of SE QID NO: 1 (exon 8)(limitations of Claim 25, 27, 29). Thus since Olopade teaches each limitation of the instant claims, Olopade anticipates the claimed invention.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 25, 27, 29, 39-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 8 of U.S.

Patent No. 5,942,393, August 24, 1999. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sequence recited in Claim 6, 8 of the '113 application, having the nucleotide sequence shown in SEQ ID NO: 1, or comprising only the exon coding regions of the nucleic acid sequence of Figure 1 would hybridize under stringent conditions to an exon of SEQ ID NO: 1.

### **Response to Arguments**

The response traverses the rejection. The response asserts, that in the event that the rejection is maintained, a terminal disclaimer will be filed. Thus for the reasons above and those already of record, the rejection is maintained.

Art Unit: 1634

***Allowable Subject Matter***

11. Claims 24, 26, 28, 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

An isolated polynucleotides consisting of nucleotides 2754-2894 of SEQ ID NO: 1 or consisting of nucleotides 1764-1953 of SEQ ID NO: 1 or consisting of nucleotides 2838-2876 of SEQ ID NO: 1 nor consisting of nucleotides 2426-2548 of SEQ ID NO: 1 has not been taught or fairly suggested by the prior art.

With respect to Claim 24, the claim is drawn to a fragment which encompasses non-coding intron sequences. The prior art does not teach a nucleic acid consisting of the particularly claimed fragment. Claims 26 and 28 are given priority to June 2, 1995 which is prior to the teaching in the art of the coding sequence. Finally, with respect to Claim 30, the prior art does not particularly identify exon 6 with the boundaries of the instant application, therefore there is no suggestion of an isolated polynucleotide fragment consisting of nucleotides 1764-1953 of SEQ ID NO: 1. Therefore, the subject matter of Claims 24, 26, 28, 30 would be allowable if written in independent form.

***Conclusion***

12. Claims 24, 26, 28, 30 are objected to as being dependent on a rejected base claim. Claims 23, 25, 27, 29, 39-40 are rejected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1634


§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Jeanine Goldberg**  
**Patent Examiner**  
August 18, 2004